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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,596	01/21/2004	Wilfred Wayne Lautt	14430.1USC1	4255

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EXAMINER	
RAE, CHARLESWORTH E	
ART UNIT	PAPER NUMBER
1611	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/761,596	LAUTT, WILFRED WAYNE	
	Examiner	Art Unit	
	Charleswort Rae	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30-39* is/are pending in the application.

4a) Of the above claim(s) *35-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/16/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments, filed 11/16/07, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of actions being applied to the instant application.

The new basis of the rejection was necessitated by the amendment. This action is made final.

Status of the Claims

Claims 30-39 are currently pending in this application and are the subject of the Office action.

Claims 35-39 are withdrawn for examination purposes for being directed to the constructively non- elected subject matter in view of the originally presented claims (see the below restriction requirement).

Claims 30-34 are presented for examination.

Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 30-34, drawn to a kit.

II. Claim 35-39, drawn to a method of increasing insulin sensitivity.

As noted above, claims 30-34 are deemed to have been elected by original presentation.

Information Disclosure Statement

It is requested that applicant submit a courtesy copy of the Form 1449 referenced in the 2-page communication entitled "Supplemental Information Disclosure Statement" received 11/16/07 as the Form 1449 has not been made part of the record.

Response to arguments/remarks

Rejection under 112, 2nd para

This rejection is withdrawn as the claim amendment renders the rejection moot.

Lack of written description rejection under 112, 1st para

This rejection is withdrawn as the claim amendment renders the rejection moot.

Rejection under 103(a)

Applicant asserts that this rejection should be withdrawn because it is rendered moot by the current kit claims (30-34) and the new method claims (35-39).

In response, the rejection is withdrawn.

Claim rejections – 35 USC 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 30-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herfindal et al. (Clinical Pharmacy and Therapeutics. Herfindal et. al. (eds.). 1992, pages 679-681), in further view of Thompson et al. (US Patent 5,187,305), and in further view of Wink, Jr. et al. (US Patent 5,789,447).

Claims 30-34 recite the term "kit." However, a kit comprising well known compositions comprising nitric oxide donors or agonists which do not further limit the functional characteristics of the composition. Thus, the term "kit" is not deemed to be patentable subject matter as the compositional embodiment would reasonably exhibit the same functional characteristics. It is noted that no patentable weight is being given to the intended use of the kit.

Herfindal et al. teach nitroglycerin sublingual tablet, oral spray, oral tablet, sustained release tablet and capsules, intravenous nitroglycerin, and dosage information (pages 680 to 681, especially page 681, col. 2). Claim 30 recites the term "injectable formulation;" claim 32 recites the term "oral dosage formulation; claims 33

and 34 recite the term "tablet or capsule." Herfindal et al. teach that intravenous nitroglycerin should be prepared in glass or non-PVC containers, because the nitroglycerin binds to PVC (page 681, col. 2, 4th para). Herfindal et al. also teach that patients prescribed sublingual nitroglycerin should be told to keep the tablets in the original glass container (page 680, col. 1, last para). The term "a first container comprising a unit dosage injectable formulation comprising an effective amount of a nitric oxide donor or nitric oxide agonist for increasing insulin sensitivity to a normal level" is construed to overlap with the teaching of Herfindal that intravenous nitroglycerin should be prepared in glass or non-PVC containers and the disclosure of the recommended dose (see page 681, col. 2, para. 4). The term "a second container comprising an oral dosage formulation comprising an effective amount of a nitric oxide donor agonist for maintaining insulin sensitivity" is construed to overlap with the teaching of Herfindal et al. that patients prescribed sublingual nitroglycerin should be told to keep the tablets in the original glass container (page 680, col. 1, last para). Claim 30 is construed to encompass all NO donors and NO agonists, including nitroglycerin.

Wink, Jr. et al. (US Patent 5,789,447) teach NO donors, including sodium nitroprusside (SNP), SIN-1, L-NAME (col. 21, line 55 to col. 22, line 2) and methods of treating oxygen free radical induced tissue damage associated with ischemia reperfusion injury comprising administering a treatment amount of a nitric oxide-containing compound sufficient to protect against oxygen free radical induced tissue damage (see reference claim 1); sodium nitrite is also disclosed (col. 22, lines 3-24).

The terms "an effective amount of the nitric oxide donor or nitric oxide agonist for increasing insulin sensitivity to a normal level" and "an effective amount of nitric oxide donor or nitric oxide agonist for maintaining insulin sensitivity" as recited in claim 30 are construed to be the functional equivalent of a nitric-oxide containing compound sufficient to protect against oxygen free radical induced tissue damage (col. 22, lines 3-24; and reference claim 1).

Thompson et al. (US Patent 5,187,305) teach SNAP for treating cardiovascular disorders (col. 1, lines 4-9), and formulations comprising said compound suitable for oral, parenteral, inhalation, sublingual administration (col. 5, line 59 to col. 6, line 66; especially col. 6, lines 16-24). Thompson et al. also teach that the formulations may be conveniently be presented in unit dosage form (col. 6, line 25-27).

Applicant's invention embodies well known NO donor compounds, which are known to be employed in the clinical setting for treating various conditions e.g. nitroglycerin is used to treat angina. Packaging of said medications in containers for clinical use is also well established in the clinical art. Although the cited references are silent regarding combining a first container comprising a unit dosage injectable formulation and a second container comprising an oral dosage formulation as claimed in the instant application to create a kit, someone of skill in the art would be motivated to combine the cited reference teachings to create the instant inventive concept to albeit provide a unit dosage of injectable nitroglycerin in a first container and a second container comprising an oral dosage formulation of a sublingual nitroglycerin tablet in order to provide a sublingual oral dose to be given immediately, followed by the start of

the injectable formulation to provide additional nitroglycerin coverage, especially to a patient who is suffering from angina who fails to respond to the initial dose of sublingual nitroglycerin tablets.

Thus, someone of skill in the art at the time the instant invention was made would have deemed it obvious to create the claimed invention with reasonable predictability.

Claim rejections – 35 USC 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 30-34 are rejected under 102(e) as being anticipated by Thomas (US Patent 6,358,536).

Thomas (US Patent 6,358,536) teaches a composition comprising an amount of a NO donor compound which is suitable for delivery to a mammal in a single dose, wherein the single dose alleviates cerebrovascular spasm but does not induce systemic hypotension or intracranial hypertension, and wherein the composition comprises at least one of nitroglycerin or SNP, or alternatively, the No donor compound comprises L-arginine and an agonist of NO synthase (col. 11, lines 42-62). Claim 31 recites the term nitroprusside or SNP). Thomas teaches NO donor compounds that may be administered adventially (col. 9, line 50-67), intrathecally (col. 10, lines 14-64),

pericaridally (col. 10, line 66 to col. 11, line 11), in the form of pharmaceutical compositions prepared, packaged, or sold in formulations suitable for oral, rectal, parenteral, ... administration (col. 14, lines 18-25), as a single unit dose or a plurality of single unit doses (col. 14, lines 26-30). Claim 30 recites the terms "unit dosage injectable formulation" and "oral dosage formulation" which overlaps with the teaching of Thomas (col. 9, line 50 to col. 11, line 11; and col. 14, lines 26-30). Thomas teaches that administration of NO donor compounds such as SNP can potentially release harmful cyanide or cyanate moieties or otherwise cause nausea; in one embodiment the NO donor compound is administered in conjunction with a cyanide or cyanate scavenger that will remove, chelate, bind, inactivate, or otherwise render cynanide compounds non-harmful (col. 12, line 38 to col. 13, line 21). In a preferred embodiment, the NO donor compound is administered in conjunction with an anti-emetic to alleviate or prevent nausea, and an oxyhemoglobin-reducing compound (e.g. sodium nitrite) to minimize the amount of oxyhemoglobin in the subarachnoid (or other) body location to which the composition is administered (col. 12, lines 47-62). Thomas teaches that NO donor compositions are preferably package as a single dose in a sealed ampule or a sealed syringe or other sealed device (col. 13, lines 9-21; and col. 17, line 58 to col. 18, line 31). Claim 1 recites the term "a first container" which is reasonably construed to the functional equivalent of a container as taught by Thomas (col. 13, lines 9-21; col. 17, line 58 to col. 18, line 31). Thomas teaches that formulations of a pharmaceutical composition suitable for parenteral administration comprise the active ingredient combined with a pharmaceutically acceptable carrier, which may be prepared,

packaged, or sold in a form suitable for bolus administration or for continuous administration; injectable formulations may be prepared, packaged, or sold in unit dosage form, such as ampules or multi-dose containers containing a preservative (col. 17, line 58 to col. 18, line 31). Thomas teaches that a formulation of a pharmaceutical composition suitable for oral administration may be prepared, packaged, or sold in the form of a discrete solid dose unit including, but not limited to, a tablet, a hard or soft capsule, each containing a predetermined amount of the active ingredient (col. 14, lines 51-56). Claim 1 recites the term "a second container" which is the functional equivalent of a pharmaceutical composition suitable for oral administration packaged ... in the form of discrete solid dose unit as taught by Thomas (col. 14, lines 51-56). The terms "an effective amount of the nitric oxide donor or nitric oxide agonist for increasing insulin sensitivity to a normal level" and "an effective amount of nitric oxide donor or nitric oxide agonist for maintaining insulin sensitivity" are construed to be the functional equivalent to a predetermined amount of active ingredient as taught by Thomas ingredient (col. 14, lines 51-56). Claims 33 and 34 recite the term "tablet or capsule," which is taught by Thomas (col. 14, lines 51-56). Also, Thomas teaches a kit comprising a NO donor compound (col. 25, lines 59-67; col. 26, lines 16-31). Claims 1-34 recite the term "kit."

Thus, claims 30-34 are found to be anticipated by the prior art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charlesworth Rae whose telephone number is 571-272-6029. The examiner can normally be reached between 9 a.m. to 5:30 p.m. Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http:pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 800-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

31 January 2008
CER

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